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ELECTRODES FOR FUNCTIONAL ELECTRICAL STIMULATION

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SECTION B. DESIGN AND FABRICATION OF ELECTRODES, LEADS AND CONNECTORS

B.2.1.2: Polymer-Metal Foil-Polymer (PMP) Cuff Electrodes

The polymer-metal foil-polymer (PMP) electrode is a novel design that attempts to improve the mechanical reliability and ease the manufacturing process of spiral nerve cuff electrodes. The electrode design relies upon laser micromachining technology applied to both metal foils and polymer-metal foil laminates. A second version of the electrode has been designed and is presently being implemented.

Previous Work

In earlier quarters, 2 different electrode designs (the PMP and the FWF), were pursued and a single electrode of each were fabricated. The results from this initial production were encouraging and demonstrated the feasibility of laser machining technology for electrode fabrication. While deficiencies in both designs and their manufacturing techniques were identified, so too were their strengths. A third electrode design, which we have designated as the PMP2 electrode, is being pursued. This electrode incorporates the advantages of the previous designs while avoiding the observed deficiencies.

Current Work

The PMP2 electrode is a combination of the two electrode designs (the PMP and the FWF) that we have investigated during this contract award. In essence, the more detailed, zig-zag electrical pathway of the PMP design is preserved, although the dimensions of the cuts have been increased so that a thicker span of platinum remains between individual cuts. However, the general layout of the FWF design, with the 4 bonding sites for the lead wires being centrally located and two contact sites lying on either side of this central core, has been adopted in this PMP2 design. An additional modification was included that was intended to provide improved stress relief at the sites where the isolation cuts are made. This modification is an indentation in the traces. This ensures that the silicone rubber will not tear. The width of the path was also increased to make the electrode more robust. Both of these modifications improve the quality and efficiency of the manufacturing process.

Production of Prototype

The plan of fabrication for the PMP2 electrode includes six laser machining steps. It also involves a new plan for shipping that protects the electrode from damage. A frame was created which will hold up to two electrodes manufactured on a single sheet of platinum foil. The frame is stainless steel and is composed of two plates which securely hold the electrodes between them after being screwed together. The frame raises the quality of the electrode by ensuring that the lamination does not stick to packing material, and that it is well protected from and possibility of bending or tearing.

Step 1: The first step in the fabrication process is for the basic structure of the electrode to be laser machined on the small sheet of platinum foil. This structure includes the traces of the paths where the current will flow, but does not yet define the four paths.

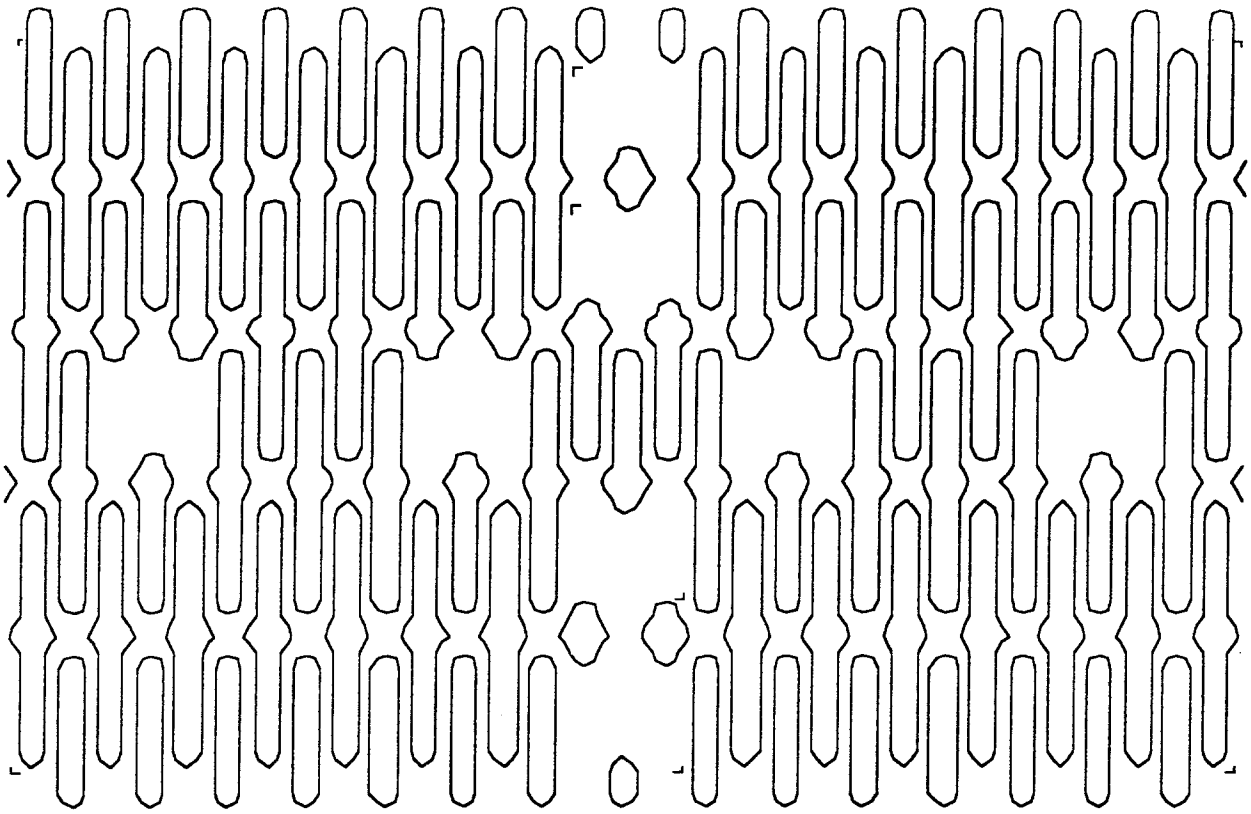

Figure 1: AutoCAD drawing showing the first cuts made by the laser to create the electrode skeleton.

Step 2: The next step is to laminate the electrode structure. This is done using cured sheeting of silicone rubber and an elastomer which fills in the holes in the foil. This lamination stage creates a flat layer of the silicone rubber, surrounding the electrode on both sides.

Step 3: The laminated electrode is then realigned on the laser and the lead, or weld, ports are removed by the laser. This removal only consists of the lamination, the platinum foil is left intact. Laser machining is also done to isolate the conducting paths. This isolation defines the paths which the current will flow through. Lastly, the excess lamination is removed from the electrode so that only the lamination covering the platinum foil remains.

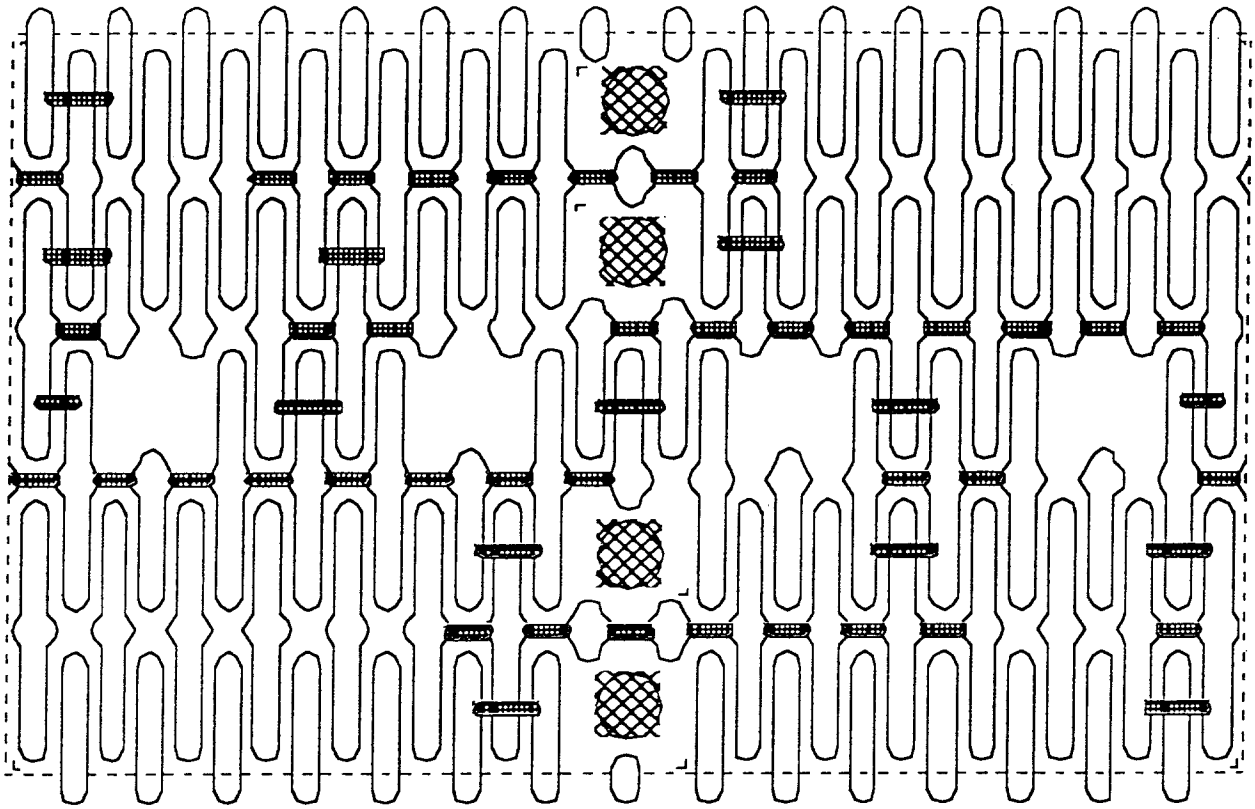

Figure 2: This AutoCAD drawing reveals the additional laser machining done in this step on the electrode and the lamination. The hatched circles shown on the lead sites represent the cutting path of the laser in removing the lamination. The small ovalular marks running horizontally on the electrode are the path isolation cuts. Lastly, this figure shows the dashed outline which signifies where the removal of the edges of the electrode and the excess lamination takes place.

Step 4: With the lead sites exposed, the leads are then welded to the electrode.

Step 5: After the leads are attached, the final lamination takes place. A single sheet of silicone rubber is laminated to the side of the electrode opposite of the leads. This sheet is also stretched so that the lamination forms a self-sizing cuff.

Step 6: The final step in the manufacturing process is to remove the lamination from the stimulation sites. This is again done with the laser machining.

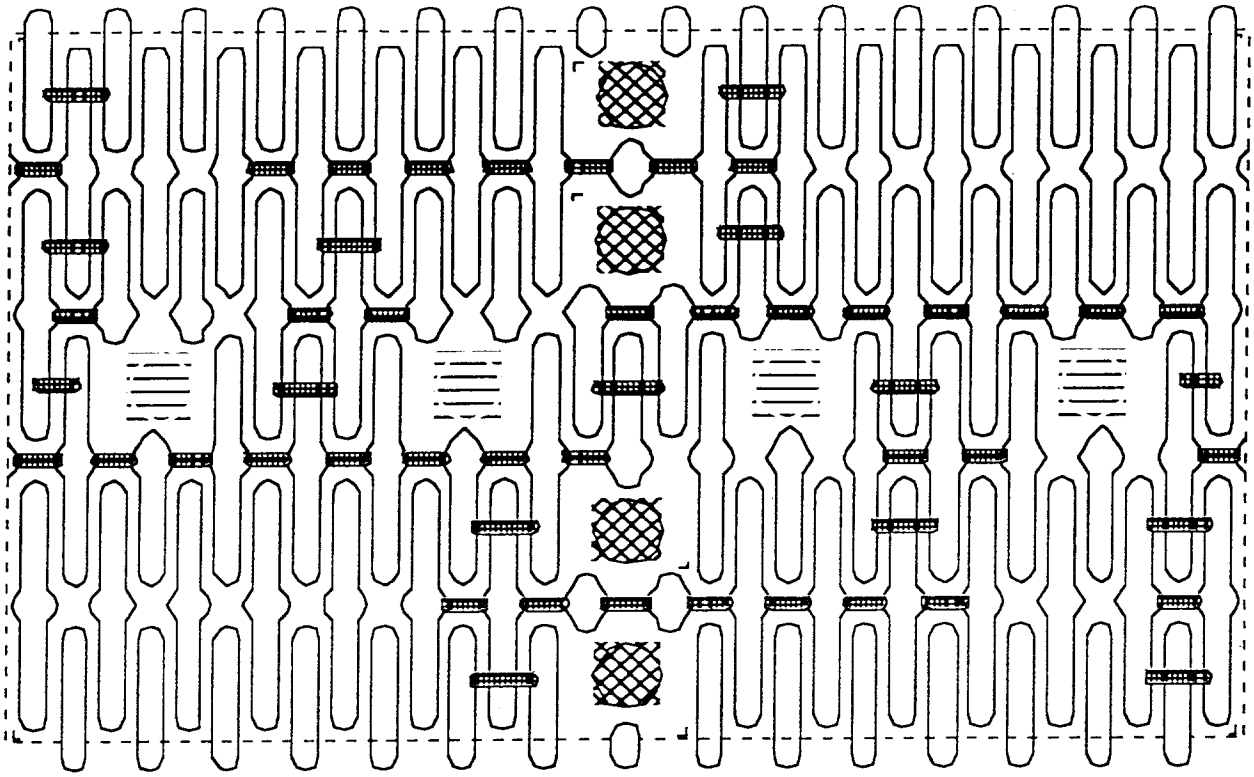

Figure 3: This drawing illustrates the removal of the lamination on the stimulation sites. These sites are shown as the hatched circles running horizontally. This figure is also a representation of all of the laser machining done on the electrode.

Fabrication Status

The first step of the fabrication process was completed with great success. Two electrodes were laser machined since two fit comfortably on one piece of platinum foil. Pictures were taken of the electrodes using an electron microscope. The results, as seen in the figures below, show excellent precision in the laser machining.

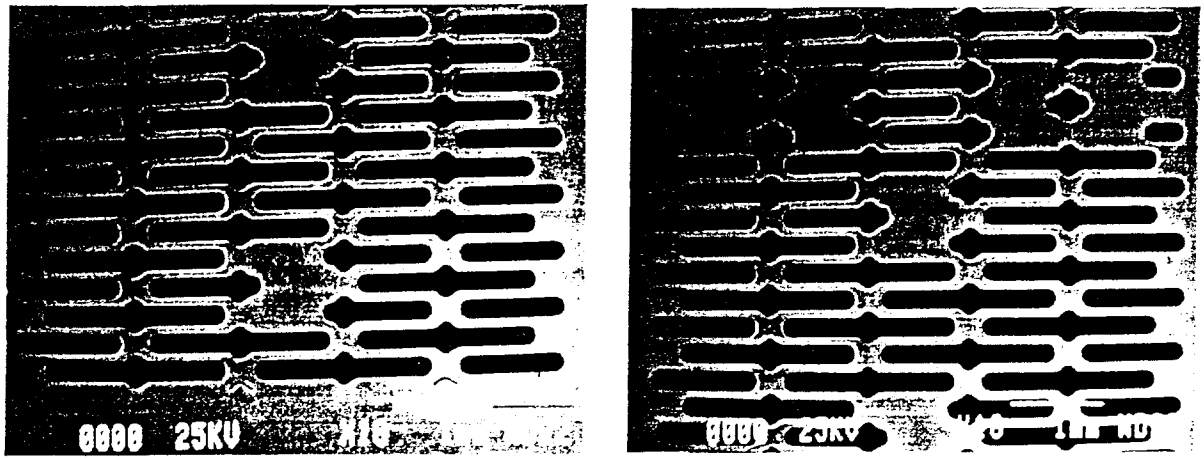

Figure 4: The two pictures above show an overview of the electrode structure. In both pictures small hash marks can be seen. These are at the bottom of the picture on the left, and on the lead welding sites on the picture on the right. These hashes were made so that the electrode could be easily aligned in the laser machine. This helps to make the process more efficient and accurate.

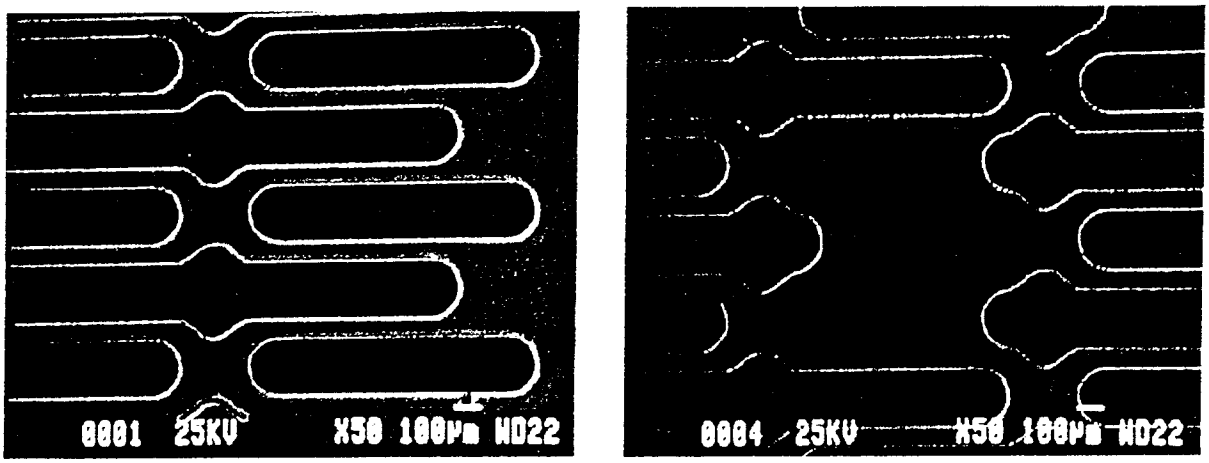

Figure 5: A closer look at the electrode reveals the precision of the laser machining. The hash marks described above can also be seen in the left-hand picture. The picture on the right focuses on one of the stimulation sites.

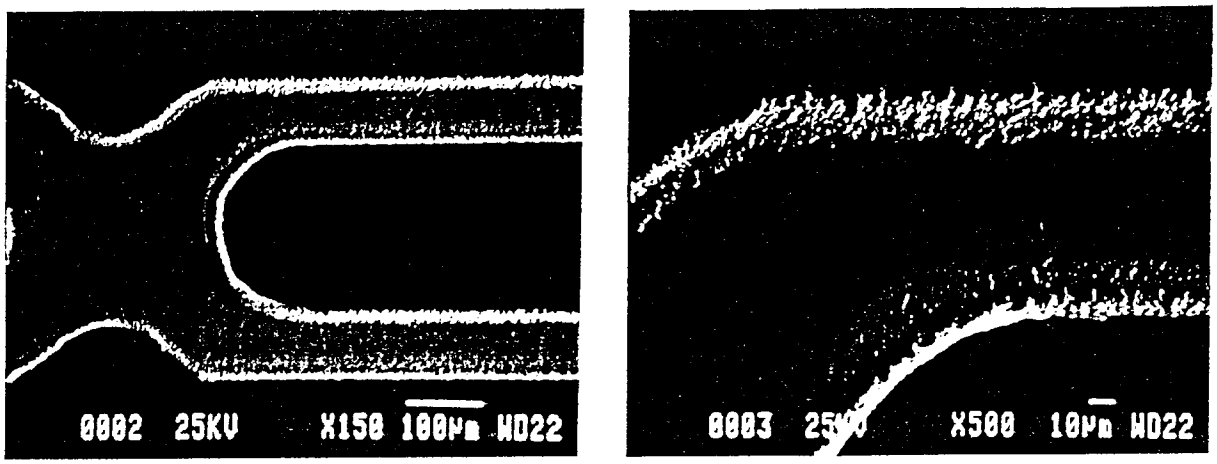

Figure 6: Lastly, even under greater magnification, the accuracy of the laser can be seen. The edges are extremely clean in comparison to other mechanical machining processes.

Step 2 of the manufacturing process was also completed. The lamination was done on the two electrodes as a unit. These electrodes will later be separated and treated as separate entities in Step 3. Pictures of the electrodes after the lamination were taken through a microscope.

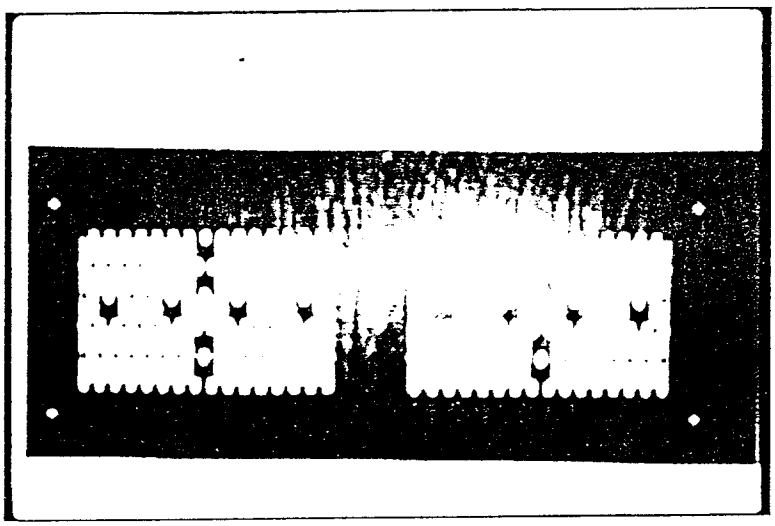

Figure 7: This picture shows how two electrodes were fabricated out of a single piece of platinum foil. The electrodes were laminated while still connected. Later steps will separate the electrodes.

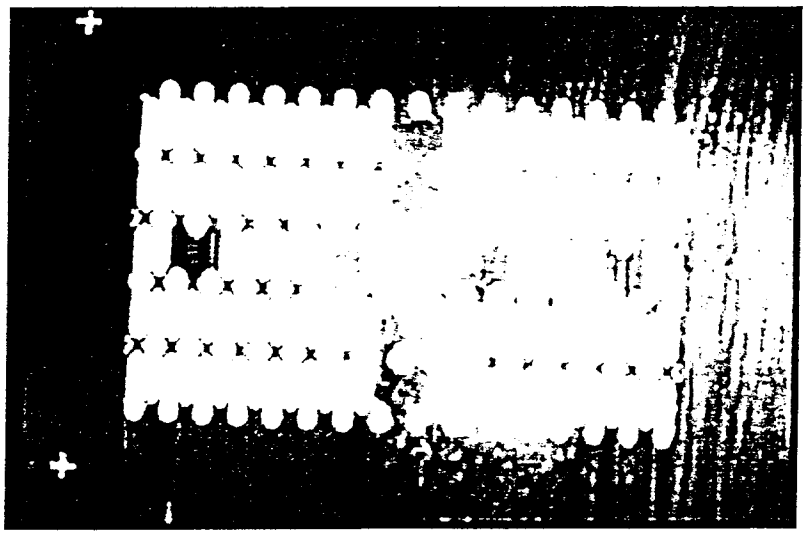

Figure 8: A close up of one of the electrodes gives a better representation of its structure as a single entity.

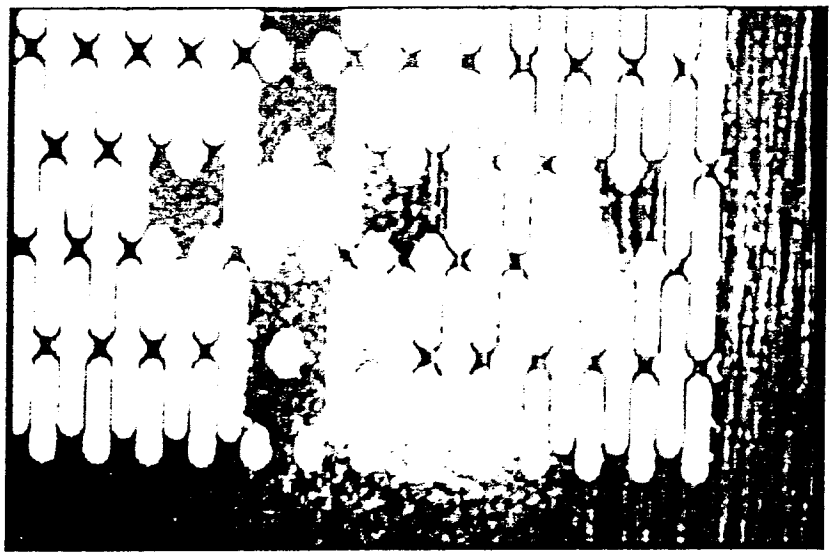

Figure 9: Further magnification gives perspective on the electrode pattern as seen in the AutoCAD drawing in Figure 1.

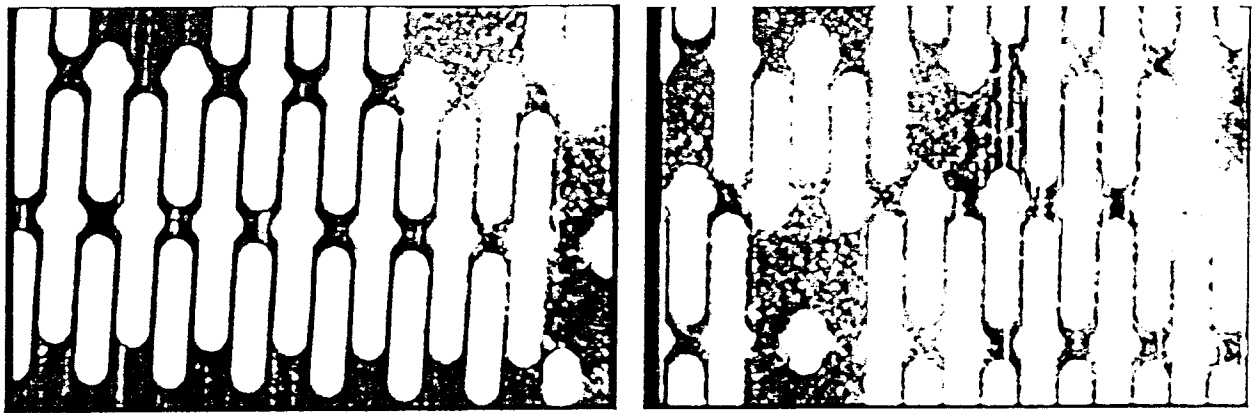

Figure 10: Magnification of the path on the left, and that lead and stimulation sites on the right, illustrates the precision of the laser cutting and the clear lamination.

Future Work

During the next quarter, Step 3 will be completed and Step 4 will be the primary focus. Step 4 involves the welding process. A new method of welding must be designed in order to weld with such a small amount of platinum foil exposed. Having the silicone rubber on both sides also complicates the welding process. A new electrode holder will be created which will allow for the electrode holders to align at the point of the weld so that the current will be able to pass through the platinum foil and create a weld. Once, the welding process is solidified, the strength of the welds will be tested to ensure the optimal parameters. Once this is complete, the cuff lamination in Step 5 will take place. Lastly, the self-sizing cuff electrode will go through the final machining process and the silicone rubber will be removed from the stimulation sites.

SECTION C. IN VIVO EVALUATION OF ELECTRODES

C.I.2.1.2: Electrode Selectivity: Adjacent and Separate Fascicles

Abstract

Applying field steering techniques to electrodes implanted on the cat sciatic nerve, we have demonstrated the ability to effect selective activation of eight of the eleven fascicles within the nerve trunks of six animals that were not accessable with single contact activation. In five of the eight cases, anodic field steering current was applied to an adjacent contact to divert the excitatory field to effect selective activation of the adjacent fascicle. In three of the eight cases, cathodic field steering from an adjacent contact was found to divert the excitatory field to effect selective activation of the adjacent fascicle. In one case, the anodic steering current from an adjacent contact was varied over a range of values to demonstrate that it is possible to effect a graded degree of selectivity. These results are consistent with the hypothesis that multi-contact self-sizing cuff electrodes can be used to effect selective and controlled electrical activation of separate fascicles in a nerve trunk serving multiple muscles.

Purpose

The purpose of this project is to demonstrate selective activation, from threshold to maximum, of any specific motor nerve contained within a major nerve serving several muscles. The model system studied uses a four contact self-sizing cuff electrode placed on the cat sciatic nerve, which contains four major branches that serve the 13 muscles controlling the torque produced about the ankle. The focus of the studies reported here was to demonstrate that either of two adjacent fasciculi, serving separate muscles, but which cannot be separately activated using conventional stimulation techniques, can be activated separately and independently with "field steering" techniques.

Progress

Data were recorded and processed from six experiments during this part of the project. The methods used are described by Grill et al.(1996). Briefly, self-sizing spiral cuff electrodes were placed on the sciatic nerve of adult cats and the ankle torque was measured in response to electrical stimuli applied to the radially spaced contacts in the cuff. The focus of our efforts during this project was to demonstrate that field steering techniques can be used to activate selectively and controllably those fascicles that could not be activated individually through stimuli applied to a single contact. In these experiments, we intended to first identify a fascicle that could not be isolated when stimuli were applied to a single contact. We then proceeded to show that the excitatory field could be shifted away from or toward the particular fascicle in a controlled manner by the application of "steering" currents (anodic or cathodic respectively) to adjacent or opposite contacts on the radially spaced array.

Experiment #5a: Cat #302

In Figure C.1 is shown the torque evoked around the ankle joint of Cat #302. The lightly grayed data were recorded when stimuli were applied to each of the branch nerves: the common peroneal (labeled **CP**), the tibial (labeled **Tib**), the medial gastrocnemius (labeled **MG**) and the lateral gastrocnemius/soleus (labeled **LG**) branches of the sciatic nerve. Neither the medial gastrocnemius nor the tibial fascicles were fully recruited using a single monopolar contact. In the case of the medial gastrocnemius no torque output trace was found to produce plantar flexion with an equivalent amount of medial rotation. In the case of the tibial the 180° position appears to activate some of the tibial but full activation of the tibial without activation of other fascicles is not achieved.

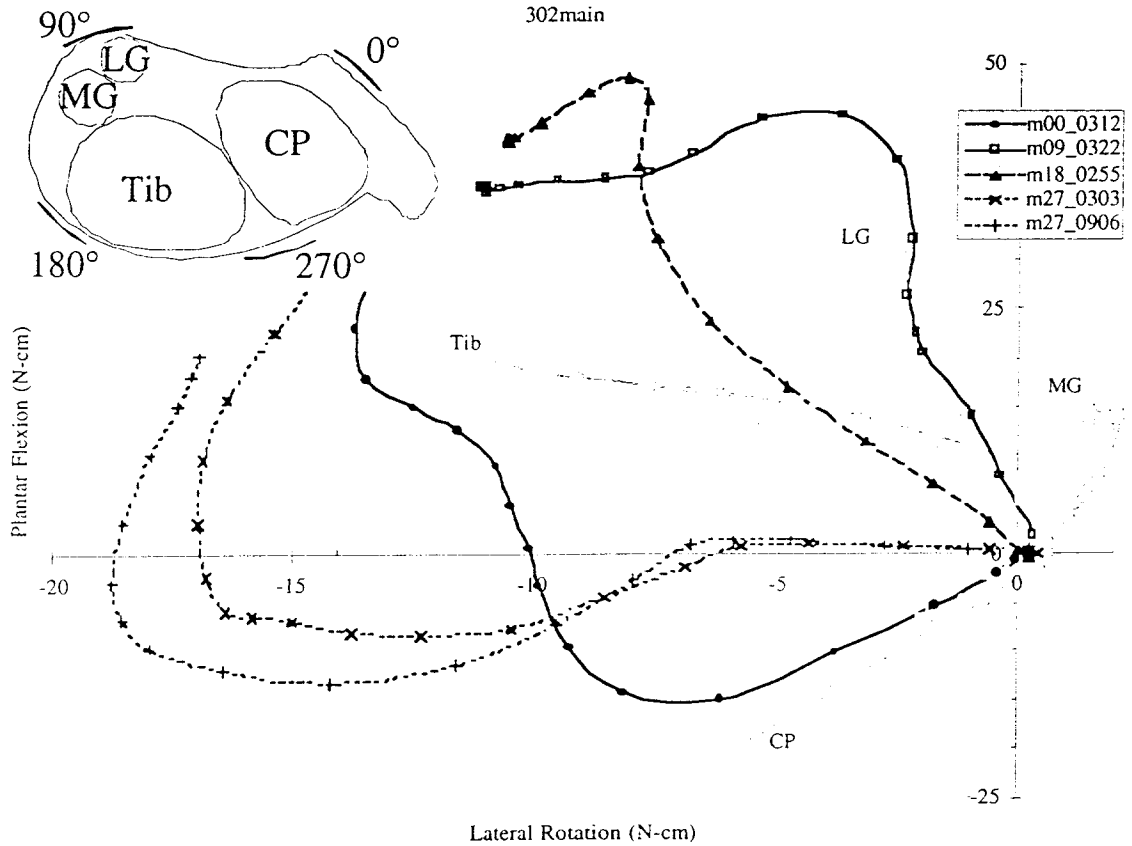

Figure C.1 - Torque output produced by stimulation of each of the branches of the sciatic in gray and monopolar stimulation of each position around the cuff on the sciatic nerve in dark lines. Each curve is labelled with a letter followed by a two digit (00, 09, 18, or 27) number corresponding to the contact position through which cathodic current passed (0°, 90°, 180° or 270° positions respectively). After the underscore (_) is the time (on a 24hr clock) at which the data were collected.

In Figure C.2 is shown the torque evoked around the ankle joint when anodic steering from the 90° or the 270° positions were added to the cathodic current at the 180° position. In the case of adding anodic current from the 270° position, a trace indicating the activation of the medial gastrocnemius was achieved. Based on the nerve cross-section we believe that the anodic current from the 270° position hyperpolarized both the tibial and the common peroneal fascicles making the medial gastrocnemius the easiest to activate. In the case of adding anodic current from the 90° position we believe the sub-fascicular axon populations within the tibial fascicle were activated in the reversed order compared to the stimulation of the tibial fascicle directly. This reversal of activation is attributed to the physical orientation of the fascicle within the sciatic nerve verses the orientation of the nerve cuff on the tibial branch. An example of another case of this reversal of activation of sub-fascicular populations is shown below in Section C.I.2.1.2, Sub-fascicular Selectivity.

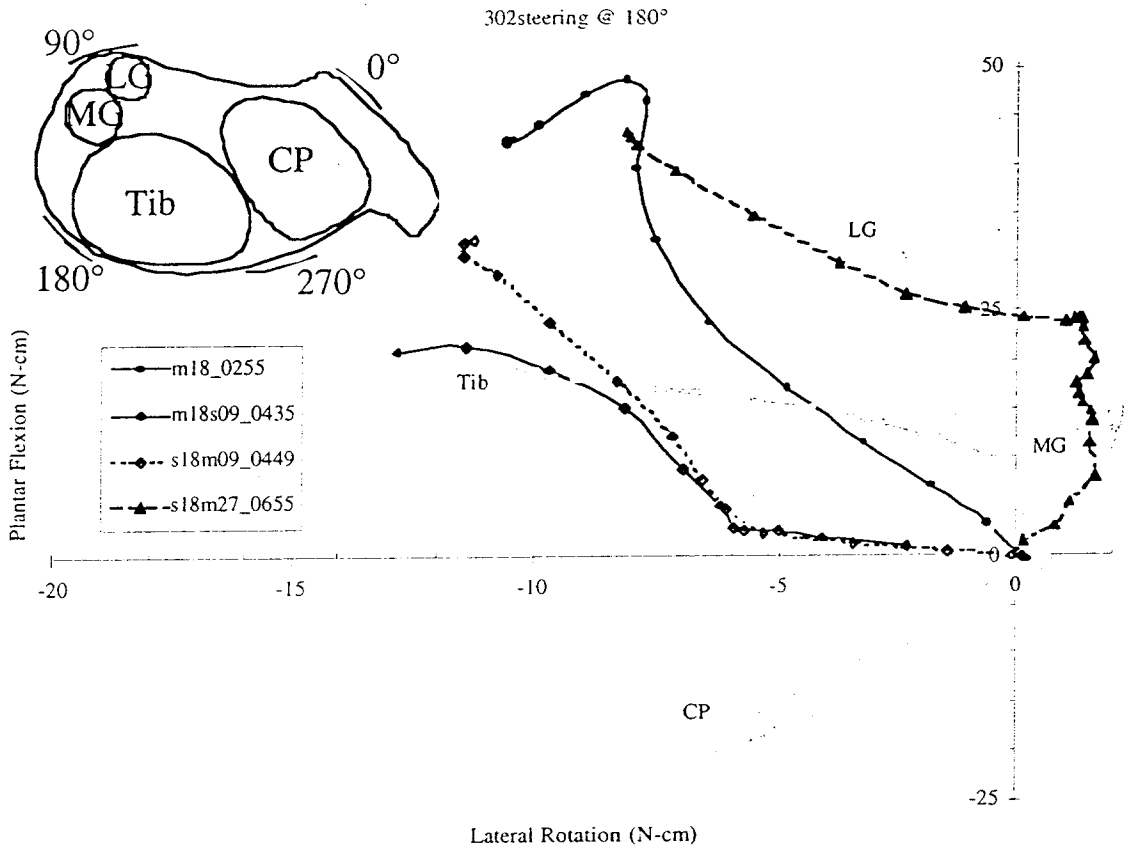

Figure C.2 - The addition of anodic steering current from the 270° position (s18m27_0655) to the 180° position was found to activate the medial gastrocnemius. The addition of anodic steering current from the 90° position (m18s09_0435 and s18m09_0449) to the 180° position was found to activate the tibial fascicle, but the sub-populations of axons were activated in the opposite order. Each curve is labelled with a letter followed by a two digit (00, 09, 18. or 27) or four digit (any combination of any two of the two digit numbers) number corresponding to either the contact position or combination of two contact positions through which cathodic current passed (0°, 90°, 180° or 270° positions respectively). If a second letter and number follows before the underscore (_), the second number represents the contact through which anodic steering current passed. After the underscore (_) is the time (on a 24hr clock) at which the data were collected.

Experiment #6: Cat #303

In Figure C.3 is shown the torque evoked around the ankle joint of Cat #303. The lightly grayed data were recorded when stimuli were applied to the medial gastrocnemius (labeled **MG**) and the lateral gastrocnemius/soleus (labeled **LG**) branches of the sciatic nerve. The medial gastrocnemius was not fully recruited using any single monopolar contact. Using a single monopolar contact, the 180° position activated some of the medial gastrocnemius but with the addition of cathodic current from the 90° position, full activation of the medial gastrocnemius was achieved (figure C.3).

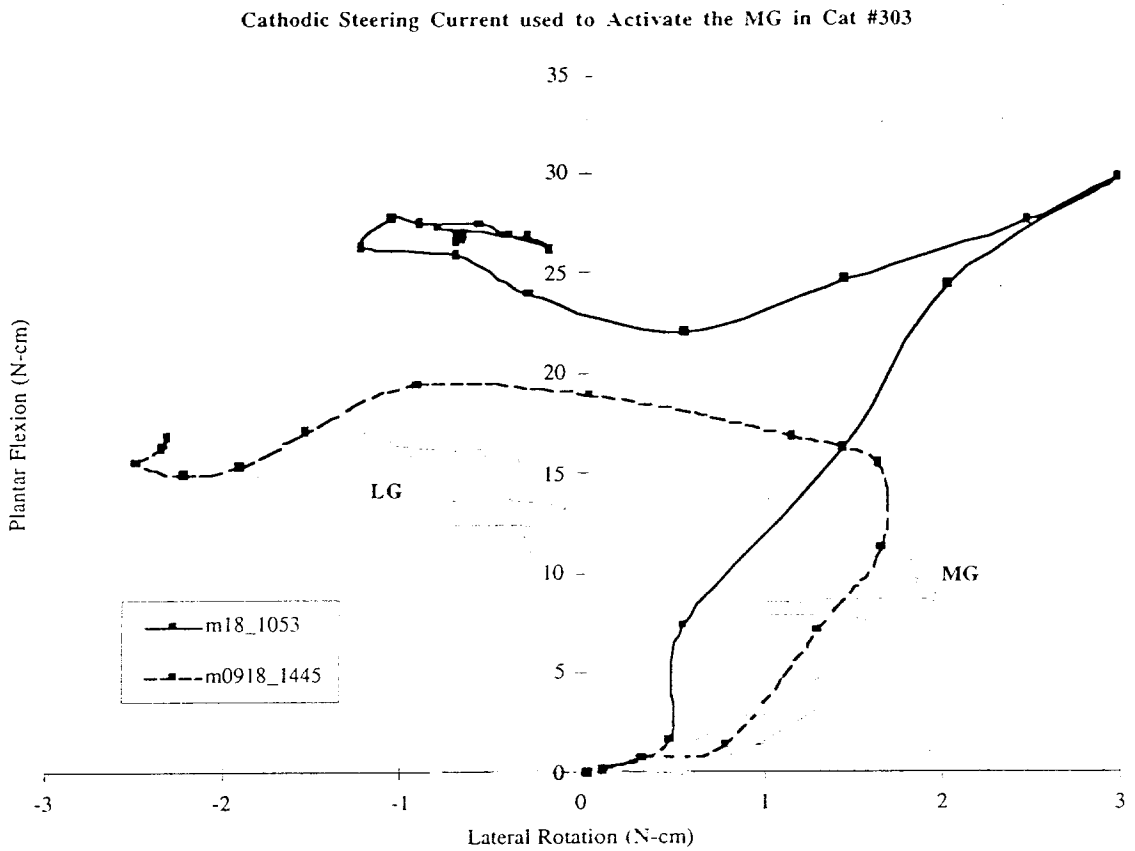

Figure C.3 - Cathodic current from the 180° position alone (m18_1053) doesn't activate the medial gastrocnemius alone. The addition of cathodic current from the 90° position (m0918_1445) evokes full activation of the medial gastrocnemius before spill-over. Each curve is labelled with a letter followed by a two digit (00, 09, 18, or 27) or four digit (any combination of any two of the two digit numbers) number corresponding to either the contact position or combination of two contact positions through which cathodic current passed (0°, 90°, 180° or 270° positions respectively). After the underscore (_) is the time (on a 24hr clock) at which the data were collected.

A brief summary of all six experiments is shown in table C.4. For each animal each fascicle is marked as either: achieved full and selective activation with single contact stimulation (o), achieved full and selective activation when anodic steering current was added (o + o) or cathodic steering was added (o - o), full and selective activation was not achieved but no steering current techniques were employed (•), or full and selective activation was not achieved even when steering current techniques were attempted (X). Thirteen of the twenty-four fascicles in six animals could be accessessed with a stimulus applied from a single contact in the self-sizing cuff electrode. Of the remaining eleven fascicles, three could be activated selectively using cathodic steering and five could be activated selectively using anodic steering. No attempt was made to isolate excitation for the other three remaing fascicles.

Cat #	Medial Gastrocnemius	Soleus/Lateral Gastrocnemius	Common Peroneal	Tibial
244	o	o	o	o + o
256	o + o	o	o	•
262	o	•	o + o	o
300	o - o	o	o	o - o
302	o + o	o	o	o + o
303	o - o	o	o	•

Table C.4 - For each animal each fascicle is marked as being achieved using: single contact stimulation (o), when anodic steering current was added (o + o) or cathodic steering was added (o - o), not achieved fully but not targeted either (•), or not achieved regardless of targeted attempt (no cases found).

Experiment #5b: Cat #302

In Figure C.5 is shown the torque evoked around the ankle joint of Cat #302. These data, although presented in the previous progress report, were reformatted for further analysis. In this animal, the 270° contact produced a torque that was characteristic of some combination of the tibial and common peroneal branches. We attempted to use steering currents to smoothly and gradually change the excitatory field of the 270° contact to activate selectively the common peroneal branch. The application of cathodic stimuli of varying amplitudes to contact 270° alone was found to produce medial rotation as shown in figure C.5 by the square and triangle data points connected by a gray line. The length of the horizontal line extending from each datum point is proportional to the amount of longitudinal current applied to achieve that output torque. The torque output produced by the application of cathodic stimuli of varying amplitudes to the common peroneal branch at three different times during the experiment is shown in the gray circles, squares, and triangles clustered near the dorsiflexion axis. The remaining data were achieved through the simultaneous application of cathodic stimuli of varying amplitudes to contact 270° and an anodic stimuli of varying amplitudes between contact 180° returning through contact 270°. The combination of stimuli produced a range of torque that encompassed the region of torque space between the torque output produced by activation of the 270° contact alone and that produced by the common peroneal branch alone. Each datum point from the combined stimulation has a line composed of a horizontal component, which is proportional to the current applied to the 270° contact, and a vertical component, which is proportional to the anodic steering current applied to the 180° contact. These vector lines indicate that an increase in the steering current and a decrease in the longitudinal contact current steers the excitatory field in the direction of the common peroneal fascicle within the nerve trunk.

These results support the hypothesis that positive steering current shifts the excitatory field away from the contact injecting the positive steering current, to favor activation of a region closer to the contact where the cathodic stimulus was applied. These results also suggest that the application of the positive steering current acts in a progressive and continuous manner to produce a gradual shift of the excitatory field.

Conclusion

Applying field steering techniques to electrodes implanted on the cat sciatic nerve, we have found it possible to effect selective activation of fascicles that were not previously accessible to electrical activation using short duration cathodic stimuli applied to a single contact of a four contact self-sizing cuff electrode. These experiments support the hypothesis that with a multi-contact, self-

sizing, spiral cuff electrode, it is possible to activate selectively, from threshold to maximum activation, any specific motor nerve contained within a major nerve serving several muscles. Additionally, we found it possible to gradually and smoothly modulate the excitatory field to move the excitation from one fascicle to a different fascicle. In some cases, the particular fascicle activated due to the addition of steering currents did not correspond to the present hypothesis of how the steering current works. Two possible explanations were proposed for these situations including inadvertent experimental error of reversing the cathodic and anodic leads from the stimulator and an incomplete understanding of field steering. In all cases, however, we found it possible to fully activate a fascicle when it was not previously possible to activate with any one contact and we found it possible to activate a single fascicle from a contact that previously activated multiple fascicles together. Future work could address how variable amounts of steering currents could be used to optimize the amount of selective control that is obtainable.

C.I.2.1.4: Electrode Selectivity: Sub-Fascicular

Abstract

Applying field steering techniques to electrodes implanted on the cat sciatic nerve, we have found it possible to increase the selective activation of nerve fibers serving one muscle in a fascicle serving many muscles within the nerve trunk. Presented here are results from two animals in which sub-fascicular selectivity was attempted. In one animal an increased separation of activation of populations within a single fascicle was achieved. The results of the second animal are inconclusive at this time. In both cases only one order of activation of the individual populations was achieved.

Purpose

The purpose of this project is to demonstrate selective activation, from threshold to maximum, of a population of motor nerves serving a single muscle and contained within a fascicle containing nerve fibers serving several muscles. The model system studied uses a four contact self-sizing cuff electrode placed on the cat sciatic nerve, which contains four major branches that serve the 13 muscles controlling the torque produced about the ankle. The focus of the studies reported here was to first show separate and distinct motor axon populations within either the common peroneal or tibial nerves. The objective was to then demonstrate that these distinct motor axon populations, serving separate muscles, could be activated separately and independently with "field steering" and/or "pre-pulse" techniques.

Background

Based on previous data collected during the present and the previous contract, we believe selective activation of muscles that are served by the same fascicle (sub-fascicular selectivity) is possible using a spiral nerve cuff electrode on the sciatic nerve. In particular, figure C.6 shows recruitment data from both the 0° contact and the tibial branch of cat #139 in which the tibial branch electrode appears to achieve a different order of axon recruitment and corresponding muscle recruitment than the sciatic nerve cuff electrode. The tibial branch data, shown in the gray, first produces medial rotational torque and then increases in plantar flexion torque. The 0° contact of the sciatic nerve cuff produces an increase in plantar flexion torque first and then produces the medial rotational torque. The difference in the recruitment between the tibial branch electrode and the 0° contact on the sciatic is attributed to spatial selectivity since no temporal differences are imposed and differences in axon size would cause both stimulation sites to recruit the same large fibers first and small fibers second. Spatial selectivity supports previous work indicating that grouping of axons within the nerve are maintained [Brushart 1991, Hallin 1990, Schady et al. 1983] and

further indicates that even inside of the perineurial scattering barrier of individual fascicles, the excitatory field affects one spatial region within that fascicle before the rest of the fascicle.

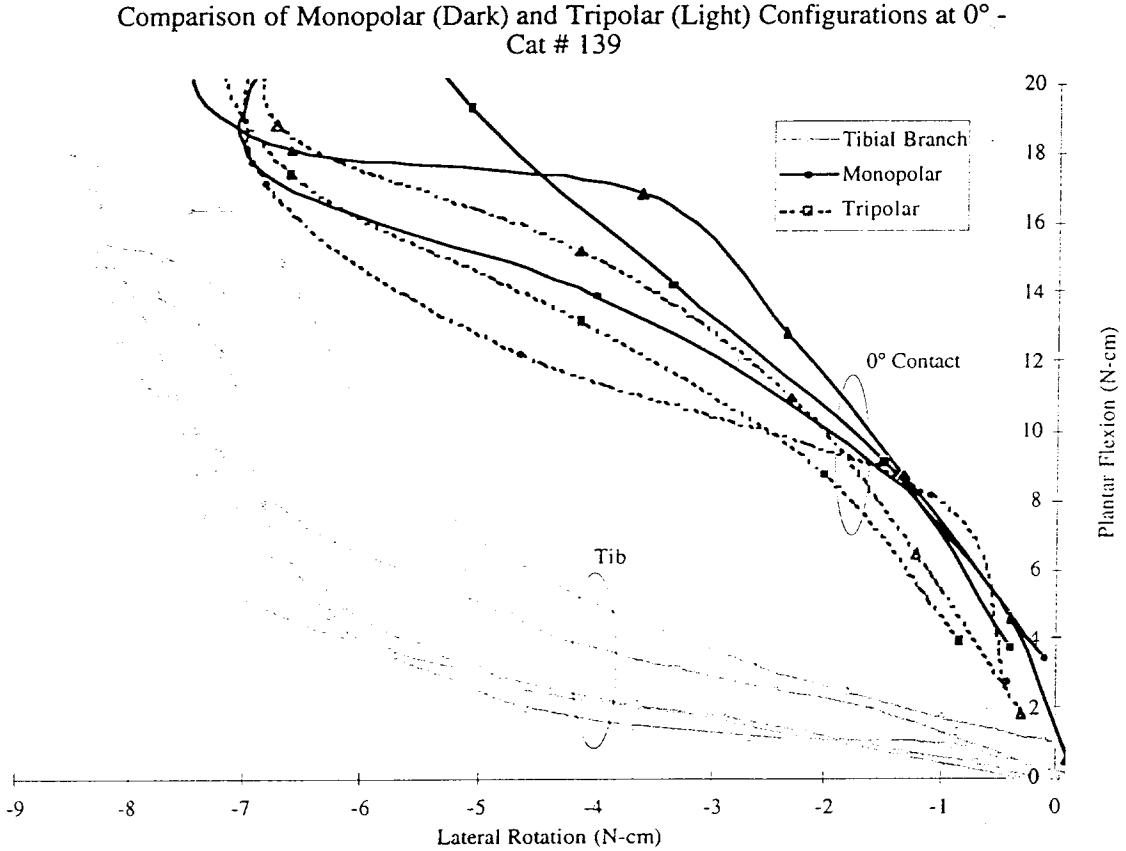

Figure C.6 - An example of how the tibial branch electrode recruited activation to produce medial rotation followed by plantar flexion while the nerve cuff electrode recruited activation to produce the plantar flexion first followed by medial rotation.

Progress

Data were recorded and processed from two experiments for this sub-fascicular project. The methods used are described by Grill et al.(1996). Briefly, self-sizing spiral cuff electrodes were placed on the sciatic nerve of adult cats and its corresponding four branches and the ankle torque was measured in response to electrical stimuli applied to the radially spaced contacts in each cuff. The focus of our efforts during this project was to demonstrate that field steering and pre-pulse techniques can be used to activate selectively and controllably distinct motor axon populations, serving separate muscles, located within a single fascicle contained within a nerve trunk serving many muscles. In these experiments, we intended to first identify a fascicle (either the common peroneal or the tibial) whose branch could be stimulated to produce torque output indicative of separate axon populations activated in two or more different orders. We then proceeded to impose field steering and pre-pulse techniques to the appropriate contact, that best activates the corresponding fascicle, to achieve separate and independent activation of the identified axon populations.

Experiment #1: Cat #315

Shown in Figure C.7 is stimulation of the common peroneal of cat #315 using different contacts placed around the branch nerve. The two different torque vectors representing the recruitment of two different muscles or muscle sets can be ascertained. Both vectors produced dorsiflexion but the vector first recruited by contacts 1&2 produced lateral rotation while the other vector, recruited first by contact 4, produced medial rotation. Regardless of the order of recruitment, each contact resulted in the same final output torque when fully saturated.

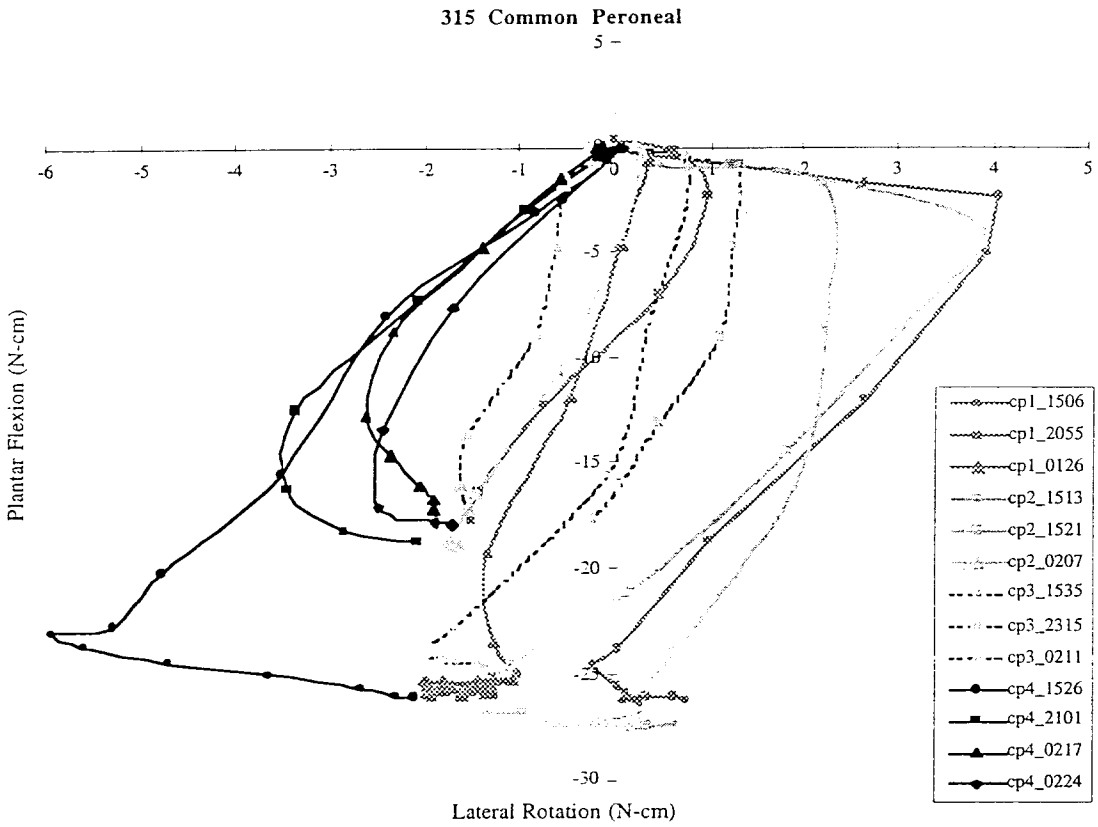

Figure C.7 - The common peroneal was stimulated with a four contact cuff electrode. Contacts number 1 and 2 show lateral rotation recruitment first while contact number 4 shows medial rotation first. Each contact saturated with the same final dorsiflexion output. Each curve is labelled with 'cp' followed by a digit corresponding to which contact within the common peroneal cuff electrode was activated. After the underscore (_) is the time (on a 24hr clock) at which the data were collected.

In Figure C.8 are shown two attempts to effect selective activation of the sub-fascicular components of the common peroneal nerve from a four contact cuff on the sciatic nerve, one using field steering and one using pre-pulse techniques. These two attempts achieved the best separate activation of the individual axon populations within common peroneal of all trials using field steering and pre-pulse techniques. In both cases the output torque was found to be closest to the output torque produced by contact 4 of the common peroneal cuff. In no case attempted was an output torque resembling contacts 1 or 2 of the common peroneal cuff, lateral rotation, achieved.

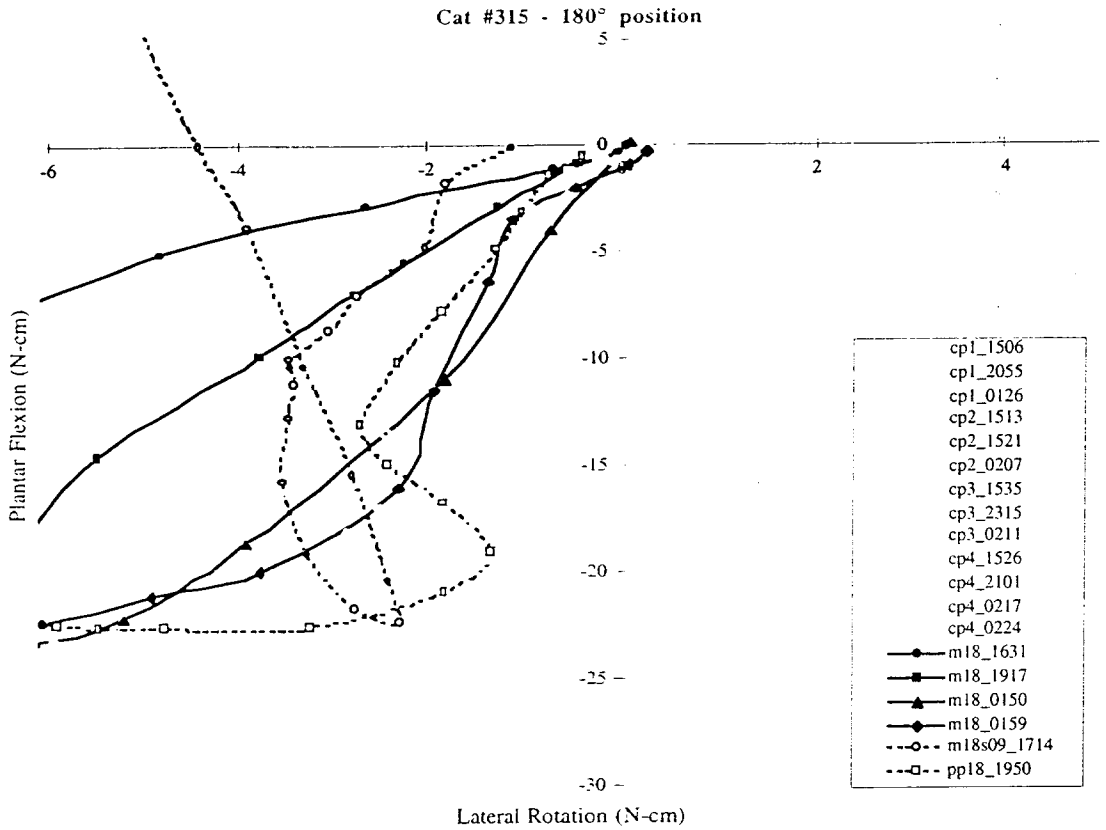

Figure C.8 - The 180° position was able to achieve most of the common peroneal fascicle using monopolar stimulation but did not achieve the same torque trace found using the individual contacts on the common peroneal branch. Using either steering from the 90° position or a depolarizing pre-pulse, a torque trace output similar to that achieve by contact #4 on the common peroneal was produced. Each curve is labelled with a letter or set of letters followed by a one digit number (in the case of the common peroneal) or a two digit (00, 09, 18, or 27) or four digit (any combination of any two of the two digit numbers) number corresponding to either the contact position or combination of two contact positions through which cathodic current passed (0°, 90°, 180° or 270° positions respectively). If a second letter and number follows before the underscore (_), the second number represents the contact through which anodic steering current passed. After the underscore (_) is the time (on a 24hr clock) at which the data were collected.

Experiment #2: Cat #363

In the second experiment, cat #363, less sub-fascicular separation was achieved using the electrodes on the branch nerves. The tibial branch nerve did show limited separation, figure C.9. The #3 and #4 contacts of the tibial cuff electrode tended to produced more plantar flexion while the #1 and #2 contacts of the tibial cuff electrode tended to produced more medial rotation first. Stimulation from the 180° position was able to achieve similar recruitment to the tibial nerve, shown in figure C.10. Anodic steering current from the 90° position was able to change the torque output trace slightly but it is not clear that additional sub-fascicular separation has occurred since the sub-fascicular selectivity achieved at the level of the branch was not as clear.

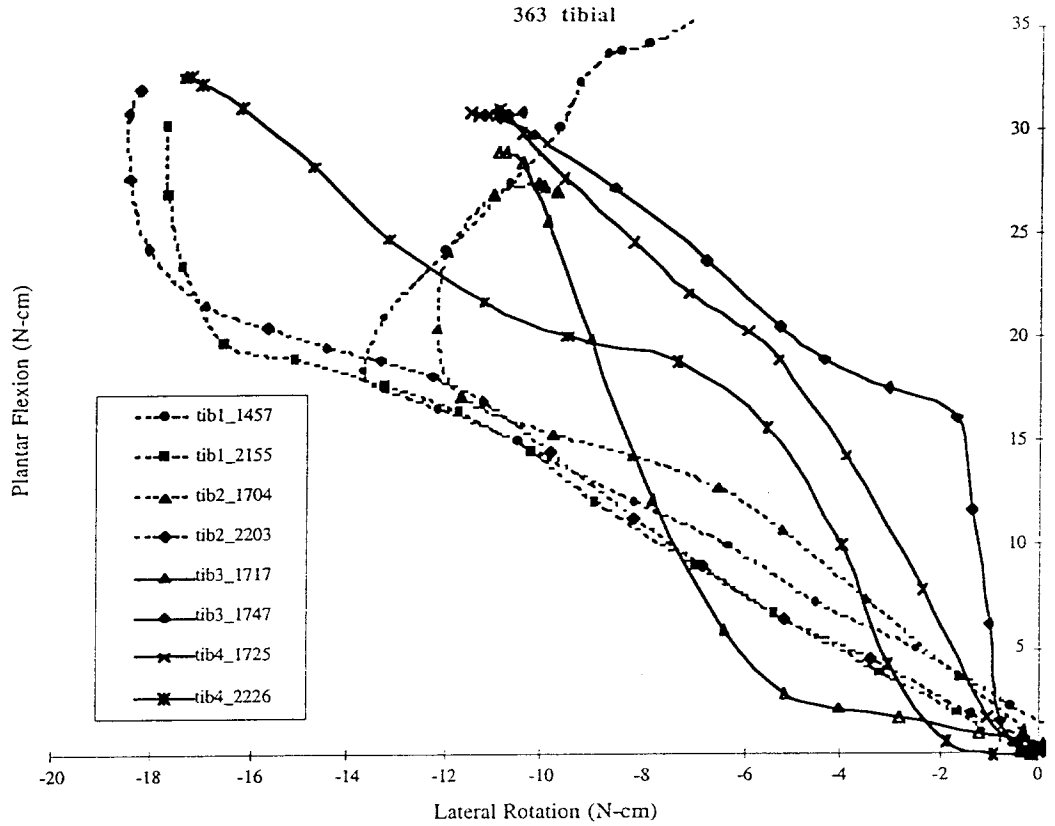

Figure C.9 - Contacts 1 and 2 on the tibial nerve shown with dashed lines do not exhibit sub-fascicular separation but contacts 3 and 4, shown with solid lines, do show some sub-fascicular separation. Each curve is labelled with 'tib' followed by a digit corresponding to which contact within the tibial cuff electrode was activated. After the underscore (_) is the time (on a 24hr clock) at which the data were collected.

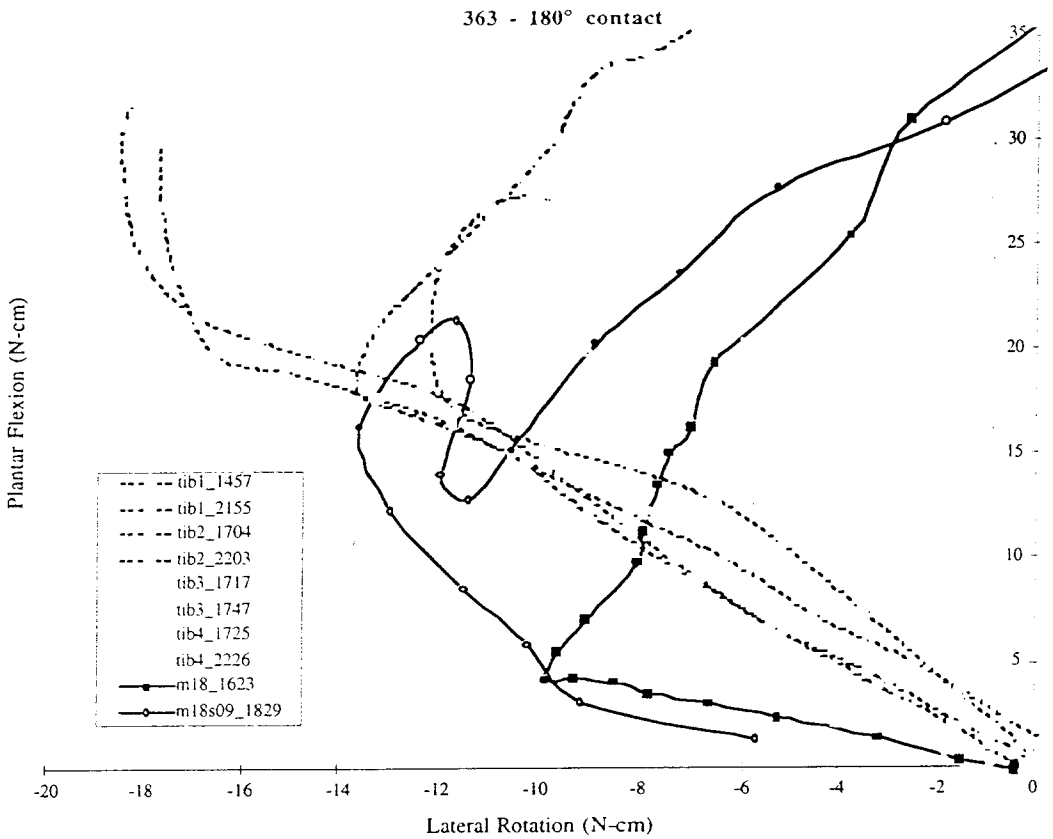

Figure C.10 - The torque traces produced using the 180° contact alone (squares with black line) and when anodic steering current from the 90° contact is added to monopolar current at the 180° position (circles with black line) is compared to the torque output produced by stimulating different contacts on the tibial branch (gray lines). Each curve is labelled with a letter or set of letters followed by a one digit number (in the case of the tibial) or a two digit (00, 09, 18, or 27) or four digit (any combination of any two of the two digit numbers) number corresponding to either the contact position or combination of two contact positions through which cathodic current passed (0°, 90°, 180° or 270° positions respectively). If a second letter and number follows before the underscore (_), the second number represents the contact through which anodic steering current passed. After the underscore (_) is the time (on a 24hr clock) at which the data were collected.

Conclusion

Although the results of these two experiments are not conclusive, these results suggest that sub-fascicular separation is feasible using steering current techniques. These results are also not exhaustive and we believe that improvements in stimulator control and improved pre-pulse techniques could be used to achieve additional selectivity of the sub-fascicular axon populations. These results do, however, indicate that selective activation of the nearest or most excitable axon population within in the fascicle does appear to be possible. Future work will attempt to refine the pre-pulse technique and use this technique to excite the more distant or less excitable populations within the fascicle before the closer or more excitable populations.

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